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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,973	12/04/2000	Nick N. Nguyen	ASP-7	3999

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,973	NGUYEN ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification does not provide an explanation for or examples for "stabilizing compounds". Thus, what stabilizing compounds represent is unclear.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, line 2; applicant uses the term "stabilizing compounds". The specification provides no explanation of such compounds. Clarification is needed to understand the meaning of claim 15.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (EP 0 321 908).

With respect to claim 1, Hatanaka teaches an apparatus for vaporizing a sterilant (figure 1, 1) including the following: an inlet (figure 2, 20), an outlet (figure 1, 13), a circuitous path (figure 2, region containing the shield disks, through 10, and through 11, and col.3, lines 15-18), and a flow restriction (figure 2, 9A).

With respect to claims 2-3 and 6, Hatanaka teaches the following: a plurality of baffles (figure 2, 9), the circuitous path includes an inner tube (figure 2, 10) positioned concentrically within an outer tube (figure 2, space containing 9), the circuitous path includes a first portion (unlabeled arrows in the space containing 9) and a second portion (figure 2, unlabeled arrows in 10), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled arrows in 14 and unlabeled arrows in space containing 9, and unlabeled arrows in 10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908).

With respect to claim 4, Hatanaka apparatus includes a portion (figure 2, unlabeled space containing 9), which increases by at least 70% or more when compared with (figure 2, 10). Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan.

With respect to claim 5, the cross-sectional area of the flow restriction (figure 1, 9A) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is well within the scope of the artisan.

With respect to claims 7-8, the restriction flow (figure 1, 9A) of Hatanaka apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time.

10. Claims 9-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908) in view of Nguyen et al (U.S.P.N. 6,279,622).

With respect to claim 9, Hatanaka discloses a method for providing a sterilant in the vapor phase (col.3, lines 24-58) including the following: creating temperature and pressure, admitting the sterilant to be vaporized, passing the sterilant through a circuitous path, passing the sterilant through a flow restriction, passing the sterilant out of the vaporizer. However, Hatanaka fails to teach applying the vapor phase sterilant to a sterilization chamber. Nguyen et al discloses applying the vapor phase sterilant to a sterilization chamber (figure 9, 110 and 115 and col.6, lines 34-36). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Hatanaka to include a sterilization chamber in order to place items in the chamber under a vacuum (Nguyen et al, col.6, lines 35-36).

With respect to claims 10-14, such claims were addressed above regarding claims 2-6 and Hatanaka, col.3, lines 24-58.

With respect to claims 17-18, Hatanaka teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of

non-vaporizable components depending on the desired quality of the discharged vapor sterilant.

With respect to claims 15-16, Hatanaka discloses using liquid hydrogen peroxide (col.3, lines 18-19) such that water is a stabilizing compound for the liquid phase of the sterilant.

With respect to claims 19-20, such claims were addressed above regarding claims 7-8 and Hatanaka, col.3, lines 24-58.

Conclusion

11. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Cummings et al (U.S.P.N. 4,956,145), Childers (WO 97/47331), and Leibold (DE 26 39 301) disclose similar apparatuses and methods for vaporizing liquid hydrogen peroxide into a vapor sterilant.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
12/09/2003

Robert J. Warden, Sr.

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